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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WHITEMAN, BRIAN A

ART UNIT

PAPER NUMBER

1635

16

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,416

Applicant(s)

XIAO, XIAO

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 18-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8-13 and 24-28 is/are rejected.
- 7) ☒ Claim(s) 3-7 and 14-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Final Rejection

Claims 1-28 are pending.

Applicant's traversal, the amendment to the specification and the amendment to claims in paper no. 14 filed on 4/3/03 is acknowledged and considered.

Election/Restrictions

This application contains claims 18-23 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 60/200,777, filed on 4/27/00. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

Art Unit: 1635

Drawings

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Objections

Claims 1-17 and 24-28 are objected to because of the following informalities: an isolated nucleotide sequence does not "encode" a minigene although they may comprise a minigene.

Claims 1-17 and 24-28 are objected to because of the following informalities: the wording of the independent claims 1 and 3 is confusing because the claims are mixing protein and nucleic acid terminology, e.g., a nucleotide sequence does not consist of an N-terminal domain, rod repeats, H1 domain, H4 domain, a cysteine-rich domain, or a C-terminal domain although an amino acid may consist of an N-terminal domain, rod repeats, H1 domain, H4

domain, a cysteine-rich domain, or a C-terminal domain. In addition, the dystrophin gene does not have a N-terminal although the dystrophin gene product may comprise a N-terminal.

The term "and/or" in Claim 4 is improper.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Applicant's arguments, see paper no. 14, filed on 4/3/03, with respect to 112 first paragraph rejection(s) have been fully considered and are persuasive. The rejection of claims 1-17 and 24-28 has been withdrawn.

Applicant's arguments, see paper no. 14, filed on 4/3/03, with respect to 112 second paragraph rejection(s) have been fully considered and are persuasive. The rejection of claims 8-13 and 24-28 has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Koenig et al. (IDS, Cell, Vol. 53:219-228, 1988). Koenig teaches the complete sequence of the human

dystrophin cDNA comprising of the N-terminal domain, rod repeats, H1 and H4 domains, Cysteine rich domain, and C-terminal domain (abstract).

Applicant's arguments filed 4/3/03 have been fully considered but they are not persuasive. MPEP 2111.03 states:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355.

Since the claims and the specification do not indicate what the basic and novel characteristics are for the claims, the term "consisting essentially of" is the equivalent of "comprising". There is no evidence in the specification or claims that the presence of additional rod repeats would materially affect the basic and novel characteristic of the claimed isolated nucleotide sequence. Therefore, the cDNA taught by Koenig anticipates the claims.

Claims 8-13 and 24-28 remain rejected under 35 U.S.C. 102(a) as being anticipated by Takeda (JP1999318467A, published on 11/24/99). Takeda teaches production of several kinds of mini-dystrophin genes having 4.5kb or less and the gene has an N-terminal, hinge 1, hinge 4, 2 or more rod-repeats, a cysteine rich domain and/or C-terminal domain (See specification). Takeda further teaches using said mini-gene for producing a recombinant adeno-associated viral (rAAV) vector comprising said mini-gene for studying *in vitro* expression of gene product (See specification). Takeda teaches a rod-shortened dystrophin encoding nucleotide sequence having 4402 base pairs that is complementary to the claimed nucleotide sequences.

To overcome the prior art rejection suggest amending claims 8-13 to read as follows --
The isolated nucleic acid sequence of claim Y (8, 9, 10, 11, 12 or 13), consisting of SEQ ID NO:
X (2, 6, 9, 10, 12, or 14) or which is the complement of SEQ ID NO: X (2, 6, 9, 10, 12, or 14) --.

Applicant's arguments filed 4/3/03 have been fully considered but they are not persuasive. The term "a complement" indicates that there is more than one complement. The sequence taught by Takeda reads on a nucleotide sequence that is complementary to any of the claimed sequences. The specification does not define the term "complementary" or what % of a nucleotide sequence is considered to be a complementary strand to the claimed nucleotide sequences. Thus, since the term "complementary" is not defined by the specification any nucleotide sequence that can form a heteroduplex with the claimed sequences reads on the claims.

In response to applicant's argument that Takeda does not show any valid evidence that the minigene is indeed functional *in vivo*. The argument is not found persuasive because MPEP § 716.01(c) states:

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

Art Unit: 1635

In addition, the article by Wang provided by the applicant teaches that, "the mini-dystrophin genes tested by Takeda were functionally similar to CT dystrophin construct, thus sufficient to restore DAP complexes" (See Wang et al., PNAS, 97:13714-13719, 2000).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Art Unit: 1635

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

Scott D. Pribe
SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER